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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/737,492	03/19/97	BURMEISTER	P 563.2-6252

EXAMINER	
PREBILIC, P	
ART UNIT	**PAPER NUMBER**
3308	5

33M1/1015

VIDAS ARRETT & STEINKRAUS
SUITE 1540
920 2ND AVENUE SOUTH
MINNEAPOLIS MN 55402-4014

DATE MAILED: 10/15/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on March 19, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-19 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-421-632/40206

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The disclosure is objected to because of the following informalities:

On page 3, lines 23-25, the "Brief Description of the Drawings" needs to discuss all figures including 8a, 8b, 9a, 9b, etc which are not discussed.

Appropriate correction is required.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 1, the preamble is indefinite because it is unclear what is being claimed due the presence of "As" at the beginning of the claim. For example, is a device being claimed or a member being claimed where the device is only inferentially set forth? Claims 2-19 are also rejected because they depend upon claim 1 which is indefinite.

With regard to claim 1, line 9, it is unclear what "further deformed" means since no deformation has taken place to the stent previous to this point in the claim.

With regard to claim 3, line 1, the language "is a spring material" is grammatically awkward and would be more understandable if it were changed to ---is made of a spring metal---; see line 2 for similar grammar.

With regard to claims 5, 6, and 9, these claims have the same problem as claim 3 which should state that the portions are made of the particular material.

With regard to claim 9, the use of "nitinol" in the claim renders it indefinite because "nitinol" is a trademark, and thus, a source of a material not a material itself.

With regard to claim 11, line 2, it is unclear what "permanent" means and how it is intended to further limit the claim structure; Furthermore, it is unclear how the stent and tubular body of this claim relates to the device and tubular shape of claim 1; it appears that some of these terms are double included by the language of claim 11.

With regard to claim 15, "comprised" should be ---further comprised---.

With regard to claims 12-19, the preamble and the word "stent" thereof does not correspond to the preamble of claim 1, and thus, it is unclear how this difference is intended to further modify the language of claim 1.

With regard to claim 16, line 1, "compositions is" does not have proper subject-verb agreement since "compositions" is plural. Furthermore, it is unclear which alloy is being further modified.

With regard to claims 17-19, it is unclear which alloy is being further modified.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8 are rejected under 35 U.S.C. 102(e) as anticipated by Cardon et al (US 5,383,892) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cardon et al (US 5,383,892) alone.

With regard to claims 1-5 and 8, Cardon et al anticipates the claim language when the "member" is interpreted to include only the self-expanding portion of Cardon et al because Cardon et al discloses that flexible stents are known and are self-expanding as those described in EP 0183372; see the whole document of Cardon et al, especially Col. 1, lines 24-30 and the figures. EP 0183372, which is apparently incorporated into Cardon et al, discloses self-expanding stents so one could consider the flexible stent portion of Cardon et al to be self-expanding; see the whole document, especially the abstract; Figure 3 and the portion of the description pertaining to Figure 3. Furthermore, the self-expanding material of Cardon et al would evidently be capable of expanding if unconstrained, that is, detached from the rigid end stent portions. Additionally, the intermediate step of partial self-expansion would inherently occur if the Cardon et al stent were tightly fit into a catheter prior to insertion, wherein the removal therefrom would permit the flexible portion to bulge somewhat.

Alternatively, if one does not consider the claim anticipated because there is no explicit teaching of a partially expanding stent with Cardon et al, the Examiner posits that the present claims are at least obviated thereby because the mere intermediate step of partial expansion is obvious in view of Cardon et al which needs to be deformably expanded most if not all the way. It would have been clearly obvious to make the graft of Cardon et al partially self-expanding so that a balloon expansion device could be more easily fit within it.

Claims 6, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardon et al (US 5,383,892) as applied to claims 1-5 and 8 above, and further in view of Hess (WO 92/193310).

Cardon et al at least obviates the claim language as set forth in the earlier rejection, but lacks the various materials (such as the different phases of austenite and martensite or the nitinol) as claimed. However, Hess teaches that it has been known to use phase changing materials of nitinol in similar stents; see the whole document, especially page 3, line 25 to page 5, line 34 and page 10, lines 3-8. Hence, it is the Examiner's position that it would have been obvious to utilize stents made of nitinol with various phases in the Cardon et al invention so that the stent could be modified, on site, to the particular situation on hand.

Claims 11-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss, can be reached on (703) 308-2702. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3308